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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,733	05/20/2005	Osamu Ohara	1254-0282PUS1	2831
2292	7590	10/18/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			GUSSOW, ANNE	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/535,733

Applicant(s)

OHARA ET AL.

Examiner

Anne M. Gussow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)                   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application         |
| Paper No(s)/Mail Date ____   | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignment</u> . |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a DNA identical or substantially identical the sequence of SEQ ID NO: 2 (an N-acetylglucosamin transferase) and having a biological activity substantially equivalent to the function of the polypeptide in SEQ ID NO: 2. In view of this Sanjanwala et al. (WO 02/46426 A2) reads on the claim. Sanjanwala et al. teach the sequence of a drug-metabolizing enzyme (SEQ ID NO: 8) that has 86.5% homology to SEQ ID NO: 2 (see enclosed sequence alignment) of the present application, this sequence is disclosed to be a beta-1,6-N-acetylglucosaminyl transferase. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked at to form a single general concept under rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 18-19, drawn to a nucleic acid, vector and transformant.

Group II, claim(s) 6-7, drawn to a polypeptide and protein.

Group III, claim(s) 8-15, drawn to an antibody.

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Group IV, claim(s) 16-17, drawn to a method of screening for binding of a substance.

Group V, claim(s) 20, drawn to a method for detecting cancer.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Sanjanwala et al., the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Groups I and II are related products. Their shared technical feature is a DNA sequence encoded by SEQ ID NO: 2, but Sanjanwala et al. teach a DNA sequence homologous to SEQ ID NO: 2. Groups II and III are related products. Their shared technical feature is an antibody, which is not required for Groups I, IV or V. Groups II, IV and V are related by product and process of making. Their shared technical feature is a peptide, which is not required for Groups I and III.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

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because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: if Group III is elected, then an election of species is necessary between the following different types of antibodies:

Species A: an antibody binding to the sequence represented by SEQ ID NO: 2

Species B: an antibody binding to the sequence represented by SEQ ID NO: 3

Species C: an antibody binding to the sequence represented by SEQ ID NO: 4

The species are independent or distinct because they are different antibodies having different structures and different properties, for example affinity and avidity.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**LARRY R. HELMS, PH.D.**  
**SUPERVISORY PATENT EXAMINER**

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## RESULT 6

US-10-433-256-8

; Sequence 8, Application US/10433256  
 ; Publication No. US20040081980A1  
 ; GENERAL INFORMATION:  
 ; APPLICANT: SANJANWALA, Madhusudan M.; YAO, Monique G.  
 ; APPLICANT: AU-YOUNG, Janice K.; BAUGHN, Mariah R.  
 ; APPLICANT: ARVIZU, Chandra S.; RING, Huijun Z.  
 ; APPLICANT: LEE, Ernestine A.; DING, Li  
 ; APPLICANT: HAFALIA, April J.A.; TANG, Y. Tom  
 ; APPLICANT: YUE, Henry; TRIBOULEY, Catherine M.  
 ; APPLICANT: LU, Dyung Aina M.; LAL, Preeti G.  
 ; APPLICANT: WARREN, Bridget A.; YANG, Junming  
 ; APPLICANT: CHAWLA, Narinder K.; NGUYEN, Danniel B.  
 ; APPLICANT: GANDHI, Ameena R.; LU, Yan  
 ; APPLICANT: ISON, Craig H.  
 ; TITLE OF INVENTION: DRUG METABOLIZING ENZYMES  
 ; FILE REFERENCE: PI-0313 USN  
 ; CURRENT APPLICATION NUMBER: US/10/433,256  
 ; CURRENT FILING DATE: 2003-05-30  
 ; PRIOR APPLICATION NUMBER: PCT/US01/47429  
 ; PRIOR FILING DATE: 2001-12-04  
 ; PRIOR APPLICATION NUMBER: US 60/254,308  
 ; PRIOR FILING DATE: 2000-12-08  
 ; PRIOR APPLICATION NUMBER: US 60/256,189  
 ; PRIOR FILING DATE: 2000-12-15  
 ; PRIOR APPLICATION NUMBER: US 60/257,713  
 ; PRIOR FILING DATE: 2000-12-21  
 ; PRIOR APPLICATION NUMBER: US 60/262,706  
 ; PRIOR FILING DATE: 2001-01-19  
 ; PRIOR APPLICATION NUMBER: US 60/266,020  
 ; PRIOR FILING DATE: 2001-02-02  
 ; NUMBER OF SEQ ID NOS: 26  
 ; SOFTWARE: PERL Program  
 ; SEQ ID NO 8  
 ; LENGTH: 821  
 ; TYPE: PRT  
 ; ORGANISM: Homo sapiens  
 ; FEATURE:  
 ; NAME/KEY: misc\_feature  
 ; OTHER INFORMATION: Incyte ID No: 7485303CD1

US-10-433-256-8

Query Match 86.5%; Score 3693; DB 4; Length 821;  
 Best Local Similarity 99.0%; Pred. No. 0;  
 Matches 682; Conservative 1; Mismatches 4; Indels 2; Gaps 1;

Qy	104	LHFPADRMPPGAGLMERIQAIAQNVSDIAVKVDQILRHSLLLHSHKVSSEGRRDQCEAPSDP	163
		:	
Db	135	IHHPHRRMPPGAGLMERIQAIAQNVSDIAVKVDQILRHSLLLHSHKVSSEGRRDQCEAPSDP	194
Qy	164	KFPDCSGKVSEWMRARWTSDFCYAFFGVDGTECSFLIYLSEVEWFCPPLPWRNQTAQRAP	223
Db	195	KFPDCSGKVSEWMRARWTSDFCYAFFGVDGTECSFLIYLSEVEWFCPPLPWRNQTAQRAP	254
Qy	224	KPLPKVQAVFRSNLSHLLDLMGSGKESLIFMKKRTKRLTAQWALAAQRLAQKLGATQRDQ	283
Db	255	KPLPKVQAVFRSNLSHLLDLMGSGKESLIFMKKRTKRLTAQWALAAQRLAQKLGATQRDQ	314
Qy	284	KQILVHIGFLTEESGDVFSRVLKGGPLGEMVQWADILTALYVLGHGLRVTVSLKELQSN	343



Db	315	KQILVHIGFLTEESGDVFSRVLKGGPLGEMVQWADILTALYVLGHGLRVTVSLKELQSN	374
Qy	344	LGVPPEGSGSCPLTMPLPFDLIYTDYHGLQQMKRHMGLSFKKYRCRIRVIDTFGTPEPAYNH	403
Db	375	LGVPPEGSGSCPLTMPLPFDLIYTDYHGLQQMKRHMGLSFKKYRCRIRVIDTFGTPEPAYNH	434
Qy	404	EEYATLHGYRTNWGYWNLNPKQFMTMFPHTPDNSFMGFVSEELNETEKRLIKGGKASNMA	463
Db	435	EEYATLHGYRTNWGYWNLNPKQFMTMFPHTPDNSFMGFVSEELNETEKRLIKGGKASNMA	494
Qy	464	VVYGKEASIWKLQGKEKFLGILNKYMEIHGTVYYESQRPPEVPAFVKNHGILLPQPEFQQL	523
Db	495	VVYGKEASIWK--GKEKFLGILNKYMEIHGTVYYESQRPPEVPAFVKNHGILLPQPEFQQL	552
Qy	524	LRKAKLFIGFGFPYEGPAPLEAIANGCIFLQSRFSPPHSSLNHEFFRGKPTSREVFSQHP	583
Db	553	LRKAKLFIGFGFPYEGPAPLEAIANGCIFLQSRFSPPHSSLNHEFFRGKPTSREVFSQHP	612
Qy	584	YAENFIGKPHVWTVDYNNSEEFEEAAIKAIMRTQVDPYLPYEYTCGMLERIHAYIQHQDF	643
Db	613	YAENFIGKPHVWTVDYNNSEEFEEAAIKAIMRTQVDPYLPYEYTCGMLERIHAYIQHQDF	672
Qy	644	CRAPDPALPEAHAPQSPFVLAPNATHLEWARNTSLAPGAWPPAHALRAWLAVPGRACDTT	703
Db	673	CRAPDPALPEAHAPQSPFVLAPNATHLEWARNTSLAPGAWPPAHALRAWLAVPGRACDTT	732
Qy	704	CLDHGLICEPSFFPFLNSQDAFLKLQVPCDSTESMNHLYPAFAQPGQECYLQKEPLLFS	763
Db	733	CLDHGLICEPSFFPFLNSQDAFLKLQVPCDSTESMNHLYPAFAQPGQECYLQKEPLLFS	792
Qy	764	CAGSNTKYRRLCPCRDFRKGQVALGQGCL	792
Db	793	CAGSNTKYRRLCPCRDFRKGQVALCQGCL	821